

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

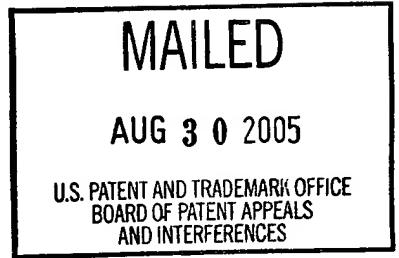
## UNITED STATES PATENT AND TRADEMARK OFFICE

### BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte GREGORY E. AGOSTON,  
JAMSHED H. SHAH, and ANTHONY M. TRESTON

Appeal No. 2005-0939  
Application No. 09/644,387

ON BRIEF



Before SCHEINER, ADAMS, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

#### DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-13 and 21-25. Claim 1 is representative of the subject matter on appeal, and reads as follows:

1. A pharmaceutical composition being substantially free of steroid contaminants having estrogenic or carcinogenic effects comprising 2-methoxyestradiol having a purity greater than 99.5% as determined by HPLC.

The examiner relies upon the following references:

Clark	5,521,168	May 28, 1996
D'Amato et al. (D'Amato)	5,504,074	Apr. 2, 1996
Fotsis et al. (Fotsis)	5,643,900	Jul. 1, 1997
Stewart	6,200,966	Mar. 13, 2001

Claims 1-13 and 21-25 stand rejected under 35 U.S.C. § 103(a) as being obvious over D'Amato, Clark, Fortis or Stewart. After careful review of the record and consideration of the issue before us, we reverse.

#### DISCUSSION

D'Amato, Clark, Fortis and Stewart are cited for teaching "the compound 2-methoxyestradiol and method(s) of using said compound in treatment of a disorder." Examiner's Answer, page 3.<sup>1</sup> The rejection concludes:

The instant claims differ from the references by reciting the compound has a purity of greater than 99.5%. However, purification of a compound to be utilized as a pharmaceutical agent would have been obvious to one having ordinary skill in the art at the time of the present invention. Therefore, the ordinary artisan in the art would have the reasonable expectation that the compound taught by the cited prior art references is in pure form.

Id.

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<sup>1</sup> The Answer then states "[s]ee each reference as indicated above in #'s 3-6." Examiner's Answer, page 3. There is not, however, any "#'s 3-6" above. We assume that the examiner is referring to the rejection as set forth in Paper No. 10, in which each of the references was separately applied under § 102. In the future, the examiner should refer to the Paper Number, or, more preferably, incorporate the teachings of each reference into the rejection set forth in the Examiner's Answer.

The burden is on the examiner to set forth a prima facie case of obviousness. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988). “A rejection based on section 103 clearly must rest on a factual basis, and these facts must be interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, all facts must be considered. The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis. To the extent the Patent Office rulings are so supported, there is no basis for resolving doubts against their correctness. Likewise, we may not resolve doubts in favor of the Patent Office determination when there are deficiencies in the record as to the necessary factual bases supporting its legal conclusion of obviousness.” In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. Denied, 389 U.S. 1057 (1968) (emphasis in original).

Appellants argue that the rejection is based on hindsight. See Appeal Brief, page 9. We agree, and the rejection is reversed.

In the case before us, the only motivation provided by the examiner for removing estrogenic or carcinogenic effects and obtaining 2-methoxyestradiol having a purity greater than 99.5% as determined by HPLC is that “purification of a compound to be utilized as a pharmaceutical agent would have been obvious to one having ordinary skill in the art at the time of the present invention.” The

examiner, however, provides no motivation as to why the ordinary artisan would want to achieve a purity of greater than 99.5%, and “conclusory statements” as to teaching, suggestion or motivation to arrive at the claimed invention “do not adequately address the issue” of obviousness. In re Lee, 277 F.3d 1338, 1343-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002).

The examiner asserts that the issue is whether the prior art makes obvious 2-methoxyestradiol having a greater than 99.5% purity, contending that:

it would take only routine experimentation to determine which impurity in a compound is harmful and, thus, removal of said impurity before utilization as a pharmaceutical agent. The motivation would be due to a desire to reduce the adverse effect(s) that might be due to the presence of said impurity. Said determination and purifications of pharmaceuticals are routine in the art and well within the level of ordinary skill of the ordinary artisan in the pharmaceutical art.

Examiner’s Answer, page 4. Citing Ex parte Gray, 10 USPQ2d 1922, 1926 (BPAI 1989), the examiner asserts further that “the mere purity of a compound, in itself, does not render a substance unobvious.” Id. at 5.

Again, as stated above, the examiner provides no teachings or suggestions that the 2-methoxyestradiol compositions taught by the prior art references have impurities that may have an adverse effect, and thus motivate the ordinary artisan to achieve a 99.5% purity. Moreover, the degree of purity of a compound can render it patentable over the same compound in a less purified state. See, e.g., In re Bergstrom, 427 F.2d 1394, 1401, 166 USPQ 256, 262, (CCPA 1970) (“[B]y definition, pure material necessarily differ from less pure or impure materials and, if the latter are the only ones existing and available as a

standard of reference, . . .perforce the 'pure' materials are 'new' with respect to them") (footnote omitted, emphasis in original). See also Genentech Inc. v. Wellcome Foundation Ltd., 29 F.3d 1555, 1562, 31 USPQ2d 1161, 1166 (Fed. Cir. 1994) (finding that in claims to an enzyme preparation having a specific recited specific activity that the specific activity limitation is "the critical distinction of those claims over the less purified materials constituting the relevant prior art.").

The examiner also contends that according to the specification,

a sample [of 2-methoxyestradiol] obtained from Sigma had a purity of 99.2% as determined by HPLC, which supports the examiner's position that the 98% is a minimum purity obtained by Sigma. The difference between 2-methoxyestradiol having a purity of 99.2%, i.e., purity of the Sigma compound identified by the present specification and a purity of greater than 99.5%, as encompassed by the instant claims, can be considered within the margin of error.

Examiner's Answer, page 5 (emphasis in original).

The examiner is apparently arguing that a purity of 99.5% as required by the claims reads on a purity of 99.2%. That reasoning, however, is relevant to a rejection under 35 U.S.C. § 102, and not to a rejection under § 103. The rejection made by the examiner in the answer is not that the claims read on 2-methoxyestradiol obtained from Sigma, but on the unsupported allegation that one of ordinary skill in the art would be motivated to purify the 2-methoxyestradiol that Stewart obtained from Sigma in order to reduce the

adverse effect(s) that might be due to the presence of said impurity.<sup>2</sup> Under that reasoning, we are compelled to reverse the rejection under 35 U.S.C. § 103.

CONCLUSION

Because the examiner failed to set forth a prima facie case of obviousness, it is reversed.

REVERSED



Toni R. Scheiner  
Administrative Patent Judge



Donald E. Adams  
Administrative Patent Judge



Lora M. Green  
Administrative Patent Judge

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) APPEALS AND

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<sup>2</sup> Moreover, there is no teaching or suggestion relied upon by the examiner that the 2-methoxyestradiol obtained from Sigma is "free of steroid contaminants having estrogenic or carcinogenic effects," as required by claim 1.

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